In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 30, 2016

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JOANN MOSTOVOY *and* VADIM MOSTOVOY, *in their own right and as best friends of their son*, V.J.M.,	No. 02-10v
Petitioners,	Chief Special Master Dorsey
v.	Study to Explore Early Development ("SEED"); Discovery; Vaccine Rule 7; Adverse Inference; Judgment as a Matter of Law
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	
* * * * * * * * * * * * * * * * * * * *	

John F. McHugh, Law Office of John McHugh, New York, NY, for petitioners.
Ann D. Martin, United States Department of Justice, Washington, DC, for respondent.

ORDER DENYING PETITIONERS' MOTION FOR SUBPOENAS AND GRANTING PETITIONERS' MOTION TO FILE DOCUMENTS OUT OF TIME[1]

On January 4, 2002, Joann Mostovoy and Vadim Mostovoy ("petitioners") brought a claim pursuant to the National Vaccine Injury Compensation Program ("the Program")[2] on behalf of their son, V.J.M. Petitioners alleged that the measles, mumps and rubella ("MMR") vaccine that V.J.M. received on January 19, 1999, caused his pervasive developmental disorder ("PDD"), an autism spectrum disorder ("ASD"). Amended Petition ¶¶ 10, 12, 15. As their theory of causation, petitioners assert that V.J.M. had an adverse reaction to human DNA found in in the rubella portion of the MMR vaccine, which triggered his ASD. Amended Petition at ¶¶ 15-16; Petitioners' ("Pet'rs'") Ex. 10 at ¶¶ 3, 17. An entitlement hearing was held in Seattle, Washington, on March 7-8, 2016. The hearing continued in Washington, D.C., on March 10-11,

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this ruling on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b).

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter "Vaccine Act" or "the Act"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

2016, and an additional day of hearing for rebuttal testimony was held on May 6, 2016, also in Washington, D.C.

Prior to the hearings, the parties were advised that "**[n]o additional exhibits** should be filed after **Friday, February 26, 2016**." Order, dated February 23, 2016, at 3 (emphasis in original). After the March 7-8 and 10-11 hearings, a status conference was held and petitioners were granted until April 15, 2016, to file additional medical literature. Order, dated March 28, 2016, at 1-2. On May 5, 2016, petitioners filed a Motion for Subpoenas and to File Documents Out of Time. Respondent filed a response on June 16, 2016, and petitioners filed a reply on July 26, 2016. For the reasons set forth below, petitioners' motions for subpoenas are denied, but the motion to file documents out of time is granted.

I. Petitioners' Motion

Petitioners accuse respondent and respondent's expert, Dr. M. Daniele Fallin, of misconduct on the grounds that neither used data from the Study to Explore Early Development ("SEED") to conduct a case-control study to test the vaccine-causation hypothesis of petitioner's expert, Dr. Theresa Deisher. See generally, Pet'rs' Motion ("Mot."); Pet'rs' Reply. In particular, petitioners allege that respondent and/or Dr. Fallin was obligated to independently analyze the results of Dr. Deisher's ecological study using SEED data. Pet'rs' Reply at 2. Petitioners state that their counsel was notified over the weekend of April 30-May 1, 2016, that in 2014, Dr. William Thompson,[3] a "Centers of Disease Control and Prevention researcher who worked in the section charged with researching vaccine safety," stated that Dr. Fallin "had access to" and "is in charge of" the SEED data. Pet'rs' Mot. at 1-2, 6. Petitioners further allege that Dr. Thompson described the SEED data, which contains vaccination records of children with autism and controls, as "the 'dream' set of data, to conduct a case-control study examining the autism-vaccine issue," but indicated that the SEED data had not and was not being used to look at the possible association of vaccines and autism. Id. at 1-4 (citing Pet'rs' Ex. 695). Dr. Fallin testified that she has conducted research on autism epidemiology funded by the CDC, including research on early development using the SEED data, but petitioners assert that Dr. Fallin "failed to mention that the SEED data contained sufficient information, including complete vaccination records, to conduct a case control study necessary to answer the precise issue before this Court." Id. at 6.

Petitioners assert that respondent is "actively working to conceal the facts relating to the relationship between vaccines and autism and to prevent the relationship from being meaningfully explored," because respondent "has control over" the SEED data, yet the data has not been produced in this proceeding nor has any study based upon it been produced. Pet'rs' Mot. at 7. Petitioners claim that the testimony of respondent's expert, Dr. Neal Halsey, and the medical article co-authored by Dr. Fallin (Pet'rs' Ex. 698), indicate that such a study could be done using the SEED data, and that according to Dr. Thompson "in the SEED dataset most of the preparatory work necessary to conduct such a study has been done. All that is left is the analysis of the information already in Dr. Fallin's control." Pet'rs' Mot. at 5-6, 8-9. Further, petitioners

[3] Dr. Thompson has not previously been identified in this case, which has now been pending since 2002, and information about Dr. Thompson's title, position, and qualifications, has not been provided. Nor has any testimony, affidavit, or other information regarding Dr. Thompson been filed.

claim that Dr. Halsey, "deems [such a study] necessary to answer the question that is before the Court in this case." Id. at 5-6.

Petitioners' motion and reply contain four different requests. First, petitioners seek to have respondent "explain why the SEED data has not been used to conduct a case control study examining the relationship between the use of human DNA-contaminated vaccines and autism." Pet'rs' Mot. at 1. In order to accomplish this, petitioners seek to have the court authorize the issuance of subpoenas to compel testimony from respondent's expert in the field of epidemiology, Dr. Fallin,[4] Dr. William Thompson, a "Centers of Disease Control and Prevention researcher who worked in the section charged with researching vaccine safety," and a representative of respondent "authorized to testify as to the composition and research use of data collected by the Study to Explore Early Development ('SEED')." Id. at 1-2.

Second, petitioners request they "be granted a presumption that [the SEED data or a case-control study based thereon] would not favor the respondent's position that the epidemic rise in autism has not been caused and is not being sustained by the mandated use of vaccines using human cell lines." Pet'rs' Reply at 14.

Third, petitioners seek leave to file four documents out of time, which purportedly support a decision to compel the requested testimony and/or a decision to draw an adverse inference against respondent:[5] (1) an excerpt from a book, "Vaccine Whistleblower," that transcribes statements purportedly made in 2014 by Dr. Thompson regarding his opinion on the potential to use the SEED database for research on vaccines and autism (Pet'rs' Ex. 695); (2) a press release from Johns Hopkins University regarding its research and development spending for the year 2012, which petitioners state "show[s] the funding received by Johns Hopkins University from the United States Government" (Pet'rs' Ex. 696); (3) a 2014 report from the United States Government Accountability Office ("GAO") on the Vaccine Injury Compensation Program (Pet'rs' Ex. 697); and (4) a paper discussing the SEED research program, titled "*Demographic Profile of Families and Children in the Study to Explore Early Development (SEED): Case-Control Study of Autism Spectrum Disorder*," published in the Disability and Health Journal, of which Dr. Fallin is a co-author (Pet'rs' Ex. 698). Pet'rs' Mot. at 2-3.

Finally, petitioners assert that "[i]n the alternative, based upon the best evidence rule and the respondent's failure to produce dispositive evidence, the petitioners are entitled to a directed verdict." Pet'rs' Mot. at 13.

II. Discussion

a. Petitioners' Motion to File Documents Out of Time

Vaccine Rule 19(b) provides that "[t]he special master of the court may grant a motion for an enlargement of time for good cause shown except when such an extension is prohibited by these rules." RCFC, Appendix B, Rule 19(b)(1).

[4] Dr. Fallin testified in this matter on March 11, 2016.

[5] These documents were filed with petitioners' motion as exhibits 695-698.

After the March 7-8 and 10-11 hearings in this case, petitioners were ordered to file additional medical literature by April 15, 2016. Order, dated March 28, 2016, at 1-2. Petitioners' Motion for Subpoenas and to File Documents Out of Time was filed on May 5, 2016. Petitioners seek to file four documents out of time, which purportedly support a decision to compel the requested testimony. Petitioners' motion does not provide an explanation as to why this information was not filed within the deadline. Rather, the motion simply states that counsel "was notified" of Dr. Thompson's statements over the weekend of April 30-May 1, 2016. Pet'rs' Mot. at 1. In her response, respondent noted that she did not object to the submission of the documents out of time for the limited purpose of considering petitioners' motion for subpoenas. Resp. Response at 2 n.2.

While there is arguably not good cause to allow the out-of-time filing of the submitted documents, the undersigned grants this request so that the articles may be considered. Petitioners filed an excerpt from the book "Vaccine Whistleblower," that transcribes statements made in 2014 by Dr. Thompson regarding his opinion on the potential to use the SEED database for research on vaccines and autism. Pet'rs' Ex. 695. Petitioners also filed a paper discussing the SEED research program, titled "Demographic profile of families and children in the Study to Explore Early Development (SEED): Case-control study of autism spectrum disorder," published in the Disability and Health Journal, and of which Dr. Fallin is a co-author. Pet'rs' Ex. 698. Petitioners state that this publication "establishes that Dr. Thompson is completely correct that this data set exists and, significantly, that it could be used to do the type of study that another witness for respondent, Dr. Halsey, deems necessary to answer the question that is before the Court in this case." Pet'rs' Mot. at 5-6. As discussed below, evidence regarding the feasibility of the requested study is not relevant to this matter because such a study has not been conducted, and is not necessary for respondent's experts to critique Dr. Deisher's study.

Finally, petitioners filed a press release from Johns Hopkins University regarding its research and development spending for the year 2012, and a 2014 report from the United States Government Accountability Office ("GAO") on the Vaccine Injury Compensation Program. Pet'rs' Exs. 696, 697. The Johns Hopkins University press release states the amount of funding the institution received from federal agencies. Pet'rs' Ex. 696 at 1. The GAO report describes steps HHS is taking to address criticism of its efforts to inform the public of the Program. Pet'rs' Ex. 697 at 36-38. Petitioners submit these exhibits as evidence that respondent's failure to conduct the requested case-control study was deliberate. See Pet'rs' Mot. at 10. Neither of these documents is evidence that respondent has deliberately sought to avoid providing evidence regarding Dr. Deisher's hypothesis. Further, even if it was evidence that respondent had a culpable state of mind, given that respondent was under no obligation to conduct the study petitioners request, evidence bearing on respondent's state of mind is not necessary for a determination of whether an adverse inference is warranted.

Petitioners' motion to file exhibits 695-698 out of time is GRANTED.

b. Petitioners' Motion for Subpoenas

Petitioners request that the court "compel Dr. Thompson to testify regarding his knowledge of the SEED data set, its capabilities and uses and [compel] Dr. Fallin and an agent of

the Secretary to explain the limitations on the use of such data." Pet'rs' Reply at 13-14. Petitioners wish to have respondent "explain why the SEED data has not been used to conduct a case control study examining the relationship between the use of human DNA-contaminated vaccines and autism." Pet'rs' Mot. at 1.

i. Legal Standard

The legal standards governing discovery[6] in Vaccine Act cases have already been thoroughly discussed in this case in the Ruling and subsequent Orders denying petitioners' motion for access to the Vaccine Safety Datalink ("VSD").[7] See Order Denying Pet'rs' Renewed Mot. for Discovery, dated Feb. 4, 2016; Order Denying Pet'rs' Mot. for Reconsideration, dated Oct. 24, 2013; Ruling, dated June 12, 2013. The standards are again summarized below.

Special masters are not governed by the Federal Rules of Civil Procedure ("FRCP"). See Order Denying Pet'rs' Renewed Mot. for Discovery, dated Feb. 4, 2016, at 4. Pursuant to the Vaccine Rule 7(a), "[t]here is no discovery as a matter of right" in Program cases. The Vaccine Act provides that "[t]here may be no discovery … other than the discovery required by the special master." 42 U.S.C. § 300aa-12(d)(3)(B)(v). A special master:

> (i) may require such evidence as may be reasonable and necessary,
> (ii) may require the submission of such information as may be reasonable and necessary, [and]
> (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary

42 U.S.C. § 300aa-12(d)(3)(B)(i)-(iii).

Pursuant to Vaccine Rule 7(a), "[t]he informal and cooperative exchange of information is the ordinary and preferred practice." However, the Vaccine Act and Vaccine Rules provide a special master with the authority to authorize formal discovery and approve the issuance of a subpoena, if the information sought is "reasonable and necessary" for the special master's resolution of contested issues. See Ruling, dated June 12, 2013, at 15-16 (citing RCFC, Appendix B, Vaccine Rule 7(c); 42 U.S.C. 300aa-§12(d)(3)(B)(iii)).

> [W]hen a special master contemplates whether to require testimony or submission of evidence, the special master: (1) must evaluate the importance and relevance of the material in question based on the overall context of the factual issues to be decided, (2) must determine whether the material is necessary to reach a fair and well-

[6] Although petitioners' reply states that their request is *not* a discovery request, a request for the authorization of subpoenas is governed by 42 U.S.C. § 300aa-12(d)(3)(B) and Vaccine Rule 7, the portion of the Vaccine Act and Vaccine Rules dealing with discovery.

[7] On February 3, 2012, petitioners filed a motion to compel discovery, seeking access to the VSD and requesting that subpoenas be issued to ten different managed care organizations.

> informed decision concerning those factual issues, and (3) must consider whether it is reasonable to require the production of the material.

Ruling, dated June 12, 2013, at 16. "The Vaccine Act's use of the terms 'necessary' and 'reasonable' indicates that the special master must apply a more rigorous standard than the 'relevance' test generally used in other litigation when deciding whether to 'require' testimony or document production." Id. "[T]he standard applied to determine whether requested material is 'necessary' in vaccine proceedings is whether, based on 'the overall context of the factual issues to be decided, the special master could not make a fair and well-informed ruling on those factual issues without the requested material.'" Id. at 17.

ii. The Requested Testimony is Not Necessary or Reasonable

Petitioners assert that respondent had an obligation to use the SEED data to produce a study that could verify or refute Dr. Deisher's ecological study, and seek to obtain testimony regarding the SEED data sets capabilities and uses. See Pet'rs' Mot. at 8 (referring to Pet'rs' Ex. 265[8]); Pet'rs' Reply at 13-14. Dr. Deisher's ecological study identified an increased rate of autism disorder in children born in certain "change point" years, a change which she theorizes can be attributed to vaccines manufactured using human fetal cell lines. See Pet'rs' Ex. 265 at 1; Pet'rs Ex. 10 at 9. Thus, petitioners argue that testimony regarding uses of the SEED data would bear on whether a study could be conducted using the SEED data that would verify or refute an epidemiological association between the introduction or increased dosage of human fetal cell line-manufactured vaccines and an increased incidence of autism.

A. The Undersigned Does Not Have the Authority to Order the Requested Study

Ordering a party to use the SEED data to produce any study is beyond the scope of the undersigned's statutory authority under the Vaccine Act. The Vaccine Act authorizes the undersigned to determine whether the petitioners are entitled to compensation based on the evidence before the court. The fact that certain studies have not been performed which may prove or disprove a theory is not relevant. Moreover, this argument, if valid, could be used in virtually every Program case. There are many mechanisms of causation for which studies have not been performed. See, e.g. Lord v. Sec'y of Health & Human Servs., No. 12-255V, 2016 WL 806818, at *17 (Fed. Cl. Spec. Mstr. 2016) (Finding existing knowledge of petitioners' causation theory about the role of cytokines in SIDS insufficient to support petitioners' causation theory "[u]ntil the role of cytokines is better understood through research").

As stated by Special Master Hastings in response to petitioners' motion for access to the VSD, a special master in the Vaccine Program may not compel a scientific study. Order Denying Pet'rs' Mot. for Reconsideration, dated Oct. 24, 2013, at 3. "[I]t is simply not appropriate to ask a special master to decide what scientific research the government should

[8] Pet'r's Ex. 265, Theresa A. Deisher, *Impact of Environmental Factors on the Prevalence of Autistic Disorder After 1979*, 6(9) J. PUB. HEALTH & EPIDEMIOLOGY 271 (2014).

undertake . . . . the decision as to how to *best allocate* scarce governmental and nongovernmental scientific resources for that purpose 'is well outside the scope of a claim brought under the Vaccine Program.'" Id. (quoting Ruling, dated June 12, 2013, at 13); see also, Werderitsh v. Sec'y of Health & Human Servs., No. 99-319V**,** 2005 WL 3320041, at *14 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (finding "that it is inappropriate for [a special master] to direct scientific research within the framework of the Vaccine Program"); Schneider v. Sec'y of Health & Human Servs.**,** No. 99-0160V, 2005 WL 318697, at *5 (Fed. Cl. Spec. Mstr. Feb. 1, 2005) ("[t]he [Vaccine] Program is not the appropriate forum for – and a special master should not preside over wide ranging discovery, or should not devise unique procedures aimed at – developing original scientific or medical theses.") Compelling a study would impose an undue burden on respondent, Dr. Fallin, and the CDC's ability to determine how to allocate time and resources, and would not be reasonable.

Even if it were appropriate to order such a study, it is not evident that the SEED data is in the control of Dr. Fallin to the extent petitioners suggest. See Resp. Response at 3-4. Dr. Fallin is one of 18 authors of *Demographic Profile of Families and Children in the Study to Explore Early Development (SEED): Case-Control Study of Autism Spectrum Disorder*. Pet'rs' Ex. 698 at 1. In addition, as respondent notes, there is substantial oversight over how the SEED data is used. The study was approved by 10 different Institutional Review Boards. Id. at 5. It is also not clear that petitioners appreciate the process involved in generating a reliable and scientifically sound case-control study. See Resp. Response at 4. Dr. Deisher testified that designing such a study using the SEED data would be "very straightforward," but respondent's expert, Dr. Halsey, testified that while it was conceivable that such a study could be designed, it "would take months to plan" and "would be a very complicated and difficult study." Id. at 4-5 (citing Tr. at 516, 817). "It might be possible to try to ask questions similar to what was done with the MMR, in a case control fashion . . . . But you're asking about at least four other vaccines that children might receive. It's not the same as one vaccine, so it's much more complicated." Tr. at 516.

Assuming that the undersigned was authorized to require the requested study, and that such a study could be designed, respondent is not obligated to conduct such a study by statute, Vaccine Rule, or any other reason. Testimony as to whether such a study is hypothetically possible, in the absence of any obligation by respondent or Dr. Fallin to produce such a study, is not necessary to the analysis of Dr. Deisher's theory. Nor is it necessary for respondent's experts to undertake an independent analysis or verification of Dr. Deisher's results in order to opine on the weaknesses of her study. Petitioners' arguments are discussed in turn, below.

B. 42 U.S.C. § 242k Does Not Impose an Obligation for Respondent to Analyze the SEED Data

Petitioners argue that it is not beyond this court's jurisdiction to order that respondent analyze the SEED data, and that it would not impose an undue burden on respondent to do so because analyzing the data is mandated by 42 U.S.C. § 242k. Pet'rs' Reply at 6. 42 U.S.C. § 242k establishes the National Center for Health Statistics ("NCHS") in the Department of Health and Human Services, and states that the Secretary, acting through the National Center for Health Statistics, "shall conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States." 42

U.S.C. § 242k(a). In carrying this out, the Secretary "shall collect statistics on . . . environmental, social, and other health hazards." 42 U.S.C. § 242k(b)(1)(C). Relying on the fact that the statute uses the word "shall," rather than "may," petitioners conclude that respondent has a statutory obligation to undertake the case-control study petitioners request. Pet'rs' Reply at 6. Petitioners' interpretation of 42 U.S.C. § 242k vastly overstates the scope of respondent's obligation to collect statistics under that statute. The statute does not impose an obligation on respondent to undertake any particular study, nor does it impose an obligation to undertake all feasible studies on all environmental hazards. It simply cannot be the case that the Secretary has a duty to undertake *all* possible research on *all* conceivable environmental, social, and other health hazards. Indeed, respondent notes that Dr. Fallin already testified as to why SEED data has not been used to conduct a case-control study examining Dr. Deisher's hypothesized relationship between vaccines derived from human cell lines and autism. Resp. Response at 7. In Dr. Fallin's opinion, if Dr. Deisher's hypothesis was correct, the case-control studies previously conducted on the MMR vaccine would have shown an association with autism, but they did not. It would be harmful to devote scientific resources to Dr. Deisher's hypothesis because "attention paid . . . to a putative cause that's not really a ca[u]se takes away attention from investigations that may lead to answers." Id. at 6-7 (citing Tr. at 732, 741-42). Thus, Dr. Fallin explains that the lack of research using the SEED data on the association between vaccines derived from human cell lines and autism represents a judgment that such a study would not be a prudent allocation of resources given the knowledge gained in prior research.

C. Informal Discovery Under the Vaccine Rules Does Not Impose an Obligation for Respondent to Analyze the SEED Data

Petitioners suggest that under the informal discovery procedures of the Vaccine Rules, respondent has an obligation to produce a case-control study based upon the SEED data. "As soon as the respondent determined that she would challenge Dr. Deisher's ecological study, her duty arose to disclose the existence of the SEED data, as did respondent's obligation to use that data to produce the kind of study that could serve to verify Dr. Deisher's results." Pet'rs' Mot. at 8. For this argument, petitioners cite the Guidelines for Practice, which state:

> There is no discovery as a matter of right in a vaccine proceeding. Because the petition and respondent's report are expected to disclose fully the substance of each party's case, there is much less need for discovery than in traditional litigation. Moreover, when one party perceives a need for further information, such information should be disclosed quickly and informally without the need for formal discovery procedures.

Id. at 7-8 (quoting Guidelines for Practice Under the National Vaccine Injury Compensation Program, Revised Apr. 21, 2016, Section IV, Ch. 5). Petitioners assert that the informal discovery under the Vaccine Act is not meant to limit access to relevant information. Pet'rs' Reply at 6 (quoting McNerney v. Sec'y of Health & Human Servs., No. 90-1689V, 1992 WL 120345 (Fed. Cl. Spec. Mstr. May 5, 1992)). The fact that informal exchange of information is preferred over formal discovery procedures, however, does not impose an obligation on respondent to conduct research to independently verify petitioners' hypothesis.

D. Criticism of Dr. Deisher's Study Does Not Require Independent Analysis of Dr. Deisher's Results

Petitioners argue that a well-informed ruling cannot be made without the required testimony "due to respondent's failure to present the best evidence." Pet'rs' Reply at 2. In particular, petitioners assert that the critique of Dr. Deisher's ecological study by respondent's experts should be discounted because none of respondent's experts independently verified Dr. Deisher's results using the data supplied by petitioner or using the SEED data. Id. at 4, 10. Again, however, respondent was under no obligation to undertake such a verification, so testimony about whether such verification could have been accomplished using the SEED data is not necessary.

Petitioners suggest that respondent's experts were under an obligation to independently verify Dr. Deisher's results because Dr. Arking indicated that verification was "required to comment competently on Dr. Deisher's work." Pet'rs' Reply at 3, 10 (citing Tr. at 631). A review of the transcript, however, reveals that Dr Arking did not indicate that analysis of the data was "required" to comment competently on Dr. Deisher's hypothesis. Dr. Arking testified: "I did say it might be useful for us to get the data and get the R code, but I **did not say we need to have it to re-analyze**, because my point on this was on its face, there is something that looks wrong." Tr. at 631 (emphasis added).

Likewise, petitioners state that Dr. Halsey "deems [a case-control study] necessary to answer the question that is before the Court in this case." Pet'rs' Mot. at 5-6. Dr. Halsey testified that autism is too rare to be detected in licensure studies and that "the next best thing we can do is in a large population, where you can capture all vaccines and all health outcomes in a retrospective cohort study, or possibly a case control study." The requested case-control study could potentially be done, but it would be very difficult and complicated, and that when you look at clinical significance in a study, "it means compared with unaffected controls." Tr. at 380, 447, 516. None of these statements, however, indicates that Dr. Halsey deems a case-control study "necessary to answer the question that is before the Court in this case." As the undersigned stated previously in this case, "[i]t is common, if not routine, for an expert to criticize the opposing expert in litigation, as well as any studies or research authored by the expert. In every hearing over which the undersigned has presided, experts have criticized the opposing experts and have testified about the inadequacy of studies presented in medical journal articles, or research performed by the opposing expert, similar to what Dr. Fallin has done here." Order Denying Pet'rs' Renewed Mot. for Discovery , Feb. 4, 2016, at 4. An expert need not undertake an independent review of the data in order to provide a critique regarding apparent methodological weaknesses of a study.

Petitioners also cite Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), to support their contention that the criticisms of respondent's experts should be disregarded. Pet'rs' Reply at 4, 10. In Daubert, the United States Supreme Court listed certain factors that federal trial courts should utilize in evaluating the admissibility of expert testimony concerning scientific knowledge. In Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize the Daubert factors as a framework for evaluating the reliability of expert testimony in vaccine

cases. The Daubert factors for analyzing the reliability of testimony are: "(1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." Terran, 195 F.3d at 1316 n.2 (citing Daubert, 509 U.S. at 592-95).

In this case, petitioners emphasize the first Daubert factor that "a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested." Pet'rs' Reply at 10 (quoting Daubert, 509 U.S. at 592-95). Petitioners note that the Court in Daubert held that "scientific knowledge" must be grounded "in the methods and procedures of science" and "more than subjective belief or unsupported speculation." Id. at 4 (quoting Daubert, 509 U.S. at 590). Because respondent's experts did not conduct the study that petitioners now request, which they allege Dr. Arking testified was "scientifically necessary" to test petitioners' theory, petitioners claim that the criticisms of Dr. Deisher's study had "no basis in the record," would be inadmissible under Daubert, and should therefore be discounted here. Id. at 2-4, 10. As discussed above, neither Dr. Arking nor Dr. Halsey's testimony supports the inference that either of them believed it was necessary to independently verify Dr. Deisher's results. Respondent's experts testified that the MMR studies were inconsistent with Dr. Deisher's study, and noted specific weaknesses in Dr. Deisher's assumptions, methodology, analysis, and conclusions. See Id. at 9; Tr. at 440-64 (Dr. Halsey's testimony); Tr. at 596-98 (Dr. Arking's testimony); Tr. at 693-707 (Dr. Fallin's testimony). Experts in this Program routinely critique medical literature submitted by the opposing party in this manner without being required to undertake an analysis of the data themselves. The fact that the author of Dr. Deisher's study was petitioners' expert does not change the requisite level of review required by respondent's experts, and their criticisms were sufficiently explained based on their expert knowledge and experience. Accordingly, testimony about whether the SEED data could have been used to conduct a case-control study to test Dr. Deisher's hypothesis is not necessary, because such a study is itself not necessary to assess Dr. Deisher's changepoint study.

The undersigned lacks the authority under the Vaccine Act to require the requested study. Further, the subpoenas requested by petitioners are not reasonable or necessary. Therefore, petitioners' motion for subpoenas is DENIED.

c. Petitioners' Request for a Presumption in Favor of Petitioner or Adverse Inference Against Respondent

i. Legal Standard

Rule 37(b)(2) of the Federal Rules of Civil Procedure permit courts to impose sanctions for failure to obey discovery orders, and even in the absence of a discovery order courts may impose sanctions for misconduct in discovery.[9] See Residential Funding Corp. v. DeGeorge Fin.

[9] In their reply, petitioners repeatedly emphasize that "[t]he present motion is not one requesting discovery, it is to compel the Secretary to produce the best evidence, which is under her control at trial." See, e.g. Pet'rs' Reply at 7. It is unclear what petitioners mean by this. An adverse inference is a

Corp., 306 F.3d 99, 106-07 (2d Cir. 2002). Appropriate sanctions include adverse inference instructions. Id. at 107. The Federal Rules of Civil Procedure do not apply in Vaccine Program cases. See, e.g. Stevens v. Sec'y of Health & Human Servs., 31 Fed. Cl. 12, 20-21 (1994). However, Rule 37(b) of the RCFC mirrors Rule 37(b) of the FRCP, and parties are permitted to move the special master to employ the discovery procedures set forth in RCFC 26-37 pursuant to Vaccine Rule 7(b)(1).

In general, a party seeking an adverse instruction on the basis that evidence was not produced in time for trial must show (1) that the party having control over the evidence had an obligation to timely produce it; (2) that the party that failed to timely produce the evidence had a "culpable state of mind"; and (3) that the missing evidence is "relevant" to the party's claim or defense such that a reasonable trier of fact could find that it would support that claim or defense. Residential Funding Corp., 306 F.3d at 107. Petitioners have not met that standard here.

ii. An Adverse Inference Is Not Warranted

Petitioners seek an adverse inference that the data and/or studies that have not been produced do not support respondent's position. Petitioners do not claim that respondent has disobeyed a particular discovery order, and for all of the same reasons discussed above, the undersigned concludes that respondent had no obligation to produce the SEED data or a study based on the SEED data in this case. Even assuming that respondent did "have control over" the SEED data as petitioners suggest, an adverse inference is not warranted because respondent had no obligation to produce it.

Petitioners' request for an adverse inference is DENIED.

d. Petitioners' Request for a Directed Verdict (Judgment as a Matter of Law)[10]

Judgment as a matter of law is not available in Vaccine cases. Under the Federal Rules of Civil Procedure, Rule 50 governs Judgment as a Matter of Law in a Jury Trial:

> If a party has been fully heard on an issue **during a jury trial** and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may:

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sanction typically imposed for misconduct in discovery. See Residential Funding Corp., 306 F.3d at 106-07. Likewise, insofar as petitioners are separately arguing that respondent should be compelled to produce the SEED data and/or studies based upon it, this is also a request for discovery.

[10] The term "Directed Verdict" is no longer used in the Federal Rules of Civil Procedure, and has been replaced by the term "Judgment as a Matter of Law." The notes to FRCP 50 explain that the term "directed verdict" was abandoned by the 1991 Amendments for a variety of reasons, but that ""if a motion is denominated a motion for directed verdict. . . the party's error is merely formal. Such a motion should be treated as a motion for judgment as a matter of law in accordance with this rule." FRCP 50, Advisory Committee Notes, 1991 Amendments, Note to Subdivision (a).

> (A) resolve the issue against the party; and
> (B) grant a motion for judgment as a matter of law against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.

FRCP Rule 50(a)(1) (emphasis added). Rule 50, however, is not incorporated into the RCFC because it applies exclusively to jury trials, which are not held in the United States Court of Federal Claims or in the Vaccine Program. See RCFC, preamble ("The Federal Rules of Civil Procedure applicable to civil actions tried by a United States district court sitting without a jury have been incorporated into the following rules to the extent appropriate for proceedings in this court."). There is no mechanism in a Vaccine Act case for petitioners to request a judgment as a matter of law in their favor after hearing.[11] Even if there were, it would be denied. Accordingly, petitioners' request for judgment as a matter of law is DENIED.

III. Conclusion

For the reasons set forth above, petitioners' motion for leave to file documents out of time is granted and their motion to issue subpoenas is DENIED.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

[11] Prior to hearing, Vaccine Rule 8(c)(d) provides that a party may make a motion for summary judgment pursuant to RCFC 56. A motion for summary judgment may be filed "at any time until 30 days after the close of all discovery." RCFC 56(b). After hearing, petitioners may file a motion for a dismissal decision or may voluntarily dismiss their own claim via stipulation with respondent. RCFC, Appendix B, Vaccine Rule 21(a)(1)(B).